IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and ABBOTT LABORATORIES, INC., Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	)	Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR)) **REDACTED PUBLIC VERSION**

MEDTRONIC VASCULAR, INC. AND MEDTRONIC USA, INC.'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR PERMANENT INJUNCTION

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Karen Jacobs Louden (#2881)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Defendants Medtronic Vascular, Inc. and Medtronic USA, Inc.

OF COUNSEL:

Kevin S. Rosen
Matthew A. Hoffman
Anthony S. Newman
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071-3197
(213) 229-7000

H. Mark Lyon
Frederick S. Chung
GIBSON, DUNN & CRUTCHER LLP
1881 Page Mill Road
Palo Alto, CA 94304-1211
(650) 849-5300

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I. SUMMARY OF ARGUMENT

Relying on an overturned legal presumption and without anything close to the supporting evidence that is required to meet their burden of proof, plaintiffs seek to compromise the public health and stifle competition by forcing Medtronic's bare-metal stents off of the market. Plaintiffs invoke this Court's equity jurisdiction in furtherance of that agenda after having waited 10 years since first accusing Medtronic of infringement (not to mention two years after the jury verdict, and months after stating their "intent" to seek injunctive relief); and they do so with unclean hands that alone compel denial of this motion. Plaintiffs' invocation of equity rings hollow, as well, given that they have licensed the same technology at issue here to the two dominant competitors in the stent market, and the fact that much of their purported evidence of irreparable harm is outdated by many years and thus is completely irrelevant.

The unique safety and efficacy attributes of Medtronic's bare-metal stents are extensively documented below and supported by numerous physician declarations and related medical literature. Ironically, even the solitary physician who purports to support plaintiffs' injunction motion admits that some of his colleagues prefer Medtronic's bare-metal stents. Of dispositive significance here as well is the fact that: (a) the PTO has preliminarily rejected the adjudicated claims of all four patents-in-suit, and (b) this Court noted that the claim construction decisions prior to and during trial were a close call, and even originally adopted Medtronic's proposed construction.

Plaintiffs' injunction motion is so plainly inadequate that it raises the specter of a reply brief that may attempt to introduce new evidence and arguments against Medtronic, in direct violation of this Court's Local Rules of Civil Practice and Procedure. *See* D. Del. LR 7.1.3(c)(2). Putting aside such anticipated transgressions, what is clear now, as explained in

greater detail below, is that plaintiffs' request for a permanent injunction respectfully must be denied for a number of independent and alternative reasons.

II. NATURE AND STAGE OF PROCEEDINGS

On December 24, 1997, Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively, "ACS"),[1] commenced this action against Medtronic Vascular, Inc. ("Medtronic Vascular") and Medtronic USA, Inc. (collectively, "Medtronic"). (*See* C.A. No. 98-314 (SLR), D.I. 1.) ACS alleged that certain of Medtronic's bare-metal stents infringed its patent rights, asserting four of these patents at trial (U.S. Patents Nos. 5,514,154, 6,066,167, 6,066,168, and 6,432,133) (collectively, "the Lau patents")). Although ACS now claims that it has been "irreparably harmed" by Medtronic's alleged infringement, ACS never sought to enjoin sales of the accused devices during the nearly ten years of litigation.

On February 18, 2005, the jury entered its verdict, finding that certain of Medtronic's accused bare-metal stent products infringe the asserted claims of the Lau patents. (D.I. 629.) Even after the verdict, and after post-trial motions were decided, ACS still did not request injunctive relief.

Judgment was entered in favor of ACS on May 3, 2007 (D.I. 715), and Medtronic filed its Notice of Appeal on May 9, 2007. (D.I. 716). That same day, counsel for ACS submitted an "E-Mail Request for Emergency Relief" notifying the Court (for the first time) of its intention "to move for a permanent injunction" and requesting that the Court "lift the stay on the damages and

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[1] Plaintiff Abbott Laboratories, Inc. acquired former plaintiff Advanced Cardiovascular Systems, Inc. from Guidant Sales Corporation ("Guidant") in April 2006 and renamed it Abbott Cardiovascular Systems, Inc. For the purposes of this brief, current plaintiffs Abbott Laboratories, Inc. and Abbott Cardiovascular Systems, Inc. and former plaintiffs Advanced Cardiovascular Systems, Inc. and Guidant shall be referred to collectively as "ACS" or "plaintiffs."

willfulness aspects of the case." (D.I. 717.) The Court responded on May 18, 2007, indicating that it was "not inclined to grant injunctive relief on these stent cases prior to appeal" and declining to "conduct a trial on willfulness and damages before final resolution on appeal." (*Id*.) Notwithstanding such guidance from this Court, ACS moved to dismiss Medtronic's appeal on June 13, 2007 (thereby delaying resolution of the appeal). The Federal Circuit granted ACS's motion on August 1, 2007.

On June 29, 2007, almost two months after ACS advised the Court of its "intention," nearly ten years after ACS filed its complaint, and more than two years after the jury verdict, ACS filed a motion for injunctive relief claiming that Medtronic's purported infringement was causing "irreparable harm" (the "Injunction Motion"). (D.I. 725.) Along with seeking an injunction against Medtronic's accused bare-metal stents, the Injunction Motion also sought to enjoin Medtronic's next-generation, soon-to-be-released drug-eluting stent Endeavor, which had never before been put at issue in this litigation.

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On August 6, 2007, this Court stayed the Injunction Motion to the extent that it relates to Endeavor and ordered that limited discovery and briefing should go forward with respect to Medtronic's bare-metal stents. (D.I. 756.)

III. STATEMENT OF FACTS

To avoid unnecessary repetition, the relevant facts are set forth in the Argument section (Part IV) below, as applicable.

IV. ARGUMENT

ACS's Injunction Motion fails in all respects to make the requisite showing under current law. "[I]njunctive relief is an extraordinary remedy." *Silverstein v. Penguin Putnam, Inc.*,

368 F.3d 77, 83-84 (2d Cir. 2004) (vacating a permanent injunction). The Supreme Court confirmed the extraordinary nature of injunctive relief in patent cases in *eBay Inc. v. MercExchange, LLC*, 126 S. Ct. 1837, 1839-40 (2006), where it rejected the Federal Circuit's "general rule" that a permanent injunction should issue upon a finding of infringement of a valid patent "absent extraordinary circumstances." Thus, the Supreme Court made clear that to obtain a permanent injunction, the burden is squarely on ACS to demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *Id.* at 1839.

For the reasons set forth below, ACS has failed to meet this standard.

A. ACS Will Not Suffer Irreparable Harm Because Money Damages Are Adequate To Compensate ACS For Medtronic's Alleged Infringement

Following *eBay*, a plaintiff seeking a permanent injunction must establish with admissible evidence that it will suffer irreparable injury absent the requested injunctive relief, and that legal remedies (such as money damages) are inadequate to compensate for that injury.[2] *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 443 (D. Del. 2007).

Attempting to satisfy its burden, ACS relies on: (1) the Federal Circuit's overturned prior practice of presuming irreparable harm upon a showing of validity and infringement; and (2) purported evidence that Medtronic's allegedly infringing stents captured market share from

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[2] Although the *eBay* Court articulated irreparable injury and inadequacy of legal remedies as two distinct prongs in its four-factor test, as ACS recognizes, "'[o]ften times the concepts of "irreparable injury" and "no adequate remedy at law" are indistinguishable' in the context of a permanent injunction." (D.I. 727 at 20 n.10); *see also MercExchange, LLC v. eBay*, 500 F. Supp. 2d 556, 569 n.11 (E.D. Va. 2007) (recognizing that "[t]he irreparable harm inquiry and remedy at law inquiry are essentially two sides of the same coin"). For this reason, the irreparable harm and no adequate remedies at law inquiries are analyzed together.

ACS's stents in the *distant past*. These arguments (and the proffered "evidence") fall far short of satisfying ACS's burden of proving irreparable harm.

Moreover, there are several other factors that are wholly inconsistent with ACS's claim that it will be irreparably harmed absent an injunction. These include: (1) ACS's history of voluntarily licensing the Lau patents to major competitors in the stent market; (2) ACS's delay of nearly ten years in seeking any form of injunctive relief against Medtronic's stents and its failure to expedite this litigation; (3) the uncertainty surrounding the outcome of this case on appeal; and (4) the questionable validity of the Lau patents themselves as preliminarily determined by the PTO. For these reasons, ACS has failed to demonstrate irreparable injury or inadequacy of legal remedies.

1. The Court Should Reject ACS's Erroneous Reliance On The Now Overturned "Presumption" Of Irreparable Harm

Despite the Supreme Court's clear holding in *eBay* that the burden is on a patent holder to establish that it is entitled to injunctive relief, ACS inexplicably attempts to invoke the Federal Circuit's pre-*eBay* practice of presuming irreparable harm upon a showing of infringement. (D.I. 727 at 18-19.) Curiously, ACS advocates presuming irreparable harm even though it acknowledges this Court's post-*eBay* holding that the "presumption that a patent holder is irreparably harmed upon a finding of infringement" is "*now-overturned*." *IMX, Inc. v. Lendingtree, LLC*, 469 F. Supp. 2d 203, 224 (D. Del. 2007) (emphasis added); *see also* D.I. 727 at 19 n.9.

eBay makes clear that the Federal Circuit's presumption of irreparable harm no longer applies. In *eBay*, the Supreme Court confirmed that the burden is on the plaintiff seeking injunctive relief to satisfy a four-factor test, which includes proof of irreparable harm, and the Court also warned against categorical rules, such as the presumption ACS advocates. *See eBay*,

126 S. Ct. at 1840-41. In addition, the Supreme Court cited its decision in *Amoco Prod. Co. v. Gambell*, 480 U.S. 531 (1987), rejecting a presumption of irreparable harm as "contrary to traditional equitable principles." 480 U.S. at 544-45.

The vast majority of district courts have agreed with this Court that *eBay* invalidated the presumption of irreparable harm. *See, e.g., Voda v. Cordis Corp.*, No. 03-1512, 2006 U.S. Dist. LEXIS 63623, at *18 (W.D. Okla. Sept. 5, 2006) (finding that the plaintiff's argument that "irreparable harm is presumed whenever validity and continuing infringement have been established" "runs afoul of the court's reasoning in *eBay*"); *Paice LLC v. Toyota Motor Corp.*, No. 04-211, 2006 U.S. Dist. LEXIS 61600, at *12 (E.D. Tex. Aug. 16, 2006) ("The *eBay* decision demonstrates that no presumption of irreparable harm should automatically follow from a finding of infringement.").

2. ACS Has Failed To Show That It Will Suffer Irreparable Harm Absent An Injunction Or That It Cannot Be Compensated By Money Damages

a. ACS's Purported *Past* Loss Of Market Share Is Not Sufficient To Show Irreparable Harm Or Inadequacy Of Legal Remedies

Attempting to show irreparable injury, ACS relies heavily on purported evidence that it lost market share to Medtronic's allegedly infringing devices *in the distant past*. But this evidence does not even remotely show that ACS will suffer *future* irreparable injury absent an injunction because: (1) ACS has recaptured nearly all of the market share it allegedly lost to Medtronic's stents; (2) ACS has not identified any specific customers it has lost (or stands to lose) as a result of Medtronic's continued sale of stents; (3) Medtronic's current share of the stent

market[3] is dwarfed by the market share of the other major stent manufacturers (including ACS); and (4) the stent market is a well-developed market with a large customer base.

According to ACS, Medtronic's release of its accused stents in 1997 and 1998 caused ACS's market share to "tumble" from 64% to 39% while Medtronic's market share "skyrocketed" to 45%. (D.I. 727 at 5-6.) ACS admits, however, that it "quickly reclaimed its lead in the stent market." (*Id*. at 6.)

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Though ACS argues that it is continuing to lose market share to Medtronic's stents, it provides no evidence other than the suggestion that there is a "significant relationship between Medtronic's market share and ACS's market share" in the bare-metal stent market[4] without reference to, or evidence of, specific customers that it has lost (or will lose).[5] (D.I. 727 at 6-7.)

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[3] Unless otherwise indicated, this brief focuses on the overall stent market (which includes both bare-metal stents and drug-eluting stents). The overall stent market is the relevant market for the purposes of ACS's Injunction Motion **REDACTED** and because, as explained below (Part IV.B.1.a., *infra*), physicians choose between drug-eluting stents and bare-metal stents for patients with coronary artery disease based on a number of factors. (Declaration of Dr. David Pearle ("Pearle Decl.") ¶ 17; *see also* Deposition Transcript of Dr. Joel Kahn, Sept. 15, 2007 ("Kahn Dep.") at 54:16-55:24 (attached as Louden Decl. Ex. B).)

[4] ACS attempts to introduce Mr. Pacitti's declaration as "evidence" that "any substantial increase in Medtronic's market share generally corresponds to a decrease in ACS's market share, and vice versa." (D.I. 729 ¶ 6). But this unqualified opinion is not based on Mr. Pacitti's personal knowledge. Instead, it is based on his parroting of Exhibit 3 to his declaration (a one-page cryptic graph), which Mr. Pacitti failed to authenticate in his declaration and as to which he failed to demonstrate any personal knowledge at his

[Footnote continued on next page]

Moreover, in so doing, ACS fails to account for the fact that the overall stent market is currently "dominated" by two other stent manufacturers (Cordis Corporation and Boston Scientific Corporation). (D.I. 727 at 10-11.) According to ACS's own evidence, in 2006, these two companies occupied 93.6% of the overall U.S. stent market as compared to 1.3% for Medtronic and 5.1% for ACS.[6] (D.I. 726 Ex. 21 at 5.)

In light of the foregoing, ACS's irreparable harm argument fails for several reasons. *First*, ACS's evidence of *past harm* does not constitute irreparable injury. Past harm is readily compensable by money damages and thus is insufficient to warrant prospective, injunction relief. *See Atlas Powder Co. v. Ireco Chems*., 773 F.2d 1230, 1233 (Fed. Cir. 1985) (recognizing that "monetary relief" – as opposed to injunctive relief – "is often the sole remedy for past infringement").

Second, because Boston Scientific and Cordis (both of which practice the Lau patents under a license from ACS) currently have a clear majority of the U.S. stent market, and because ACS's share of the market is much larger than Medtronic's, it is highly unlikely that Medtronic's

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deposition. (Deposition Transcript of David Pacitti, Sept. 29, 2007 ("Pacitti Dep.") at 95:8–96:6) (attached as Louden Decl. Ex. C).) As a result, both the exhibit and Mr. Pacitti's opinions based on the exhibit are inadmissible and cannot satisfy ACS's burden. *See* Fed. R. Evid. 602, 901.

5 ACS may not use its reply brief to present evidence of lost customers or to compensate for any of the other evidentiary shortcomings in its opening brief. *See* D. Del. LR 7.1.3(c)(2) ("The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.").

6 In the bare-metal stent market, Medtronic's market share was 17% in 2006 as compared to 63% for ACS and 21% for Boston Scientific. (D.I. Ex. 21 at 5.) Cordis no longer offers a bare-metal stent for sale in the United States. (Kahn Dep. at 4:22-5:15) (attached as Louden Decl. Ex. B).) However, as previously noted (*see* footnote 3, *supra*), the relevant market for purposes of this Injunction Motion is the overall stent market.

stents will have any significant continuing effect on ACS's market share. ACS certainly has not proven otherwise. Several courts have held that an injunction is improper where the purported infringer has a relatively small market share as compared to the patent holder and there are several other non-infringing competitors in the marketplace. *See Rosemount, Inc. v. United States Int'l Trade Comm'n*, 910 F.2d 819, 821 (Fed. Cir. 1990) (affirming the denial of a preliminary injunction, notwithstanding the patent holder's strong showing of success on the merits, in part, because the alleged infringer had a very small U.S. market share as compared to the patent holder and there were several major non-infringing competitors);[7] *Sundance, Inc. v. Demonte Fabricating Ltd.*, No. 02-73543, 2007 U.S. Dist. LEXIS 158, at *7-*8 (E.D. Mich. Jan. 4, 2007) (rejecting the patent holder's argument that its licensees suffered a competitive disadvantage due to sales of the alleged infringing product because the relevant market contained many other competitors with a larger market share than the defendant, who could have been responsible for the licensees' lost sales); *Arthrex, Inc. v. dj Orthopedics LLC*, No. 02-67, 2002 U.S. Dist. LEXIS 7634, at *12 (D. Del. Apr. 30, 2002) (finding that it was highly unlikely that the patent holder would be irreparably injured if the allegedly infringing product continued to gain market share because the patent holder had a much larger market share than the alleged infringer).

Third, the mature (rather than developing) nature of the stent market militates against a finding of irreparable harm. As this Court has recognized, since *eBay*, some courts that have

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[7] Although this decision (and several of the other judicial opinions cited herein) resolved a motion for a preliminary (rather than a permanent) injunction, such decisions are highly relevant to this motion, as "[t]he standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success." *Amoco*, 480 U.S. at 546 n.12.

permanently enjoined direct competitors "cite as their paramount consideration the fact that the parties were direct competitors in a *developing market with a small customer base*." *IMX, Inc. v. Lendingtree, LLC*, No. 03-1067-SLR, D.I. 306 at 3 (D. Del. Apr. 25, 2007) (attached as Louden Decl. Ex. D).) *See, e.g., TiVo v. EchoStar Commc'ns Corp*., 446 F. Supp. 2d 664, 669-70 (E.D. Tex. 2006) (granting a permanent injunction because the parties were direct competitors in the "nascent" digital video recorder (DVR) market, and the plaintiff was "losing market share at a critical time in the *market's development*, market share that it will not have the same opportunity to capture once the market matures.") (emphasis added).[8]

ACS rightly does not suggest that the market for bare-metal stents is anything other than fully developed. Unlike the market in *TiVo*, it is not a "critical time" in the development of the stent market (or the development of ACS's market share), as stents have been available to the public for over a decade. (*See* D.I. 727 at 3-4.) In addition, the customer base in the stent market is quite large; stents were used in nearly 90 percent of the 1.09 million angioplasty procedures performed in the United States in 2006, with total sales of approximately $3.14 billion. (D.I. 726 Ex. 21 at 5; s*ee also IMX*, No. 03-1067, D.I. 306 at 3 (attached as Louden Decl. Ex. D).)

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Fourth, even putting aside all of the foregoing, the "loss of market share alone is insufficient to support a finding of irreparable harm." *Arthrex*, 2002 U.S. Dist. LEXIS 7634, at

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[8] This Court also referred to *TiVo* in its *IMX* decision. ACS cites three opinions from the Eastern District of Texas that appear to rely exclusively on *TiVo* to support its claim that Medtronic's stents should be enjoined because they directly compete with ACS's products. (*See* D.I. 727 at 15.)

*12; s*ee also Abbott Labs. v. Andrx Pharms., Inc*., 452 F.3d 1331, 1334, 1348 (Fed. Cir. 2006) (rejecting Abbott's argument that it would be irreparably harmed absent a preliminary injunction due to "'irreversible market share losses'" because although competition from the accused product would "impact Abbott's sales . . . that alone does not establish that Abbott's harm will be irreparable."); *Am. Cyanamid Co. v. U.S. Surgical Corp*., 833 F. Supp. 92, 132 (D. Conn. 1992) ("Since market share is measured by sales, money damages are generally ascertainable for the loss of market share.").

Contrary to ACS's suggestion (D.I. 727 at 15), whether Medtronic and ACS are "head-to-head competitors" does not alter the foregoing analysis, and it certainly does not establish irreparable harm.[9] *See MercExchange*, 500 F. Supp. 2d at 577 ("[D]istrict court decisions subsequent to the Supreme Court's opinion [in *eBay*] have rejected the broad classification that direct competitors always suffer irreparable harm from infringement . . . ."); *Praxair*, 479 F. Supp. 2d at 443-44 (finding that the patent holder failed to meet its burden based on the mere assertion that it directly competes with the alleged infringer and would "likely lose additional market share, profits, and goodwill."); *Cordis Corp. v. Adv. Cardiovascular Sys., Inc*., No. 97-550, 1998 U.S. Dist. LEXIS 11342, at *30 (D. Del. July 17, 1998) (recognizing that "to a great extent" the "harms" caused by an alleged infringer's competing product "can be addressed by money damages.").

Accordingly, because (1) the stent market is large and well-developed, (2) Medtronic's stents currently have a very small share of this market, and (3) ACS has failed to present any evidence of specific customers that it has lost (or stands to lose), or any other direct evidence of a

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[9] Any such rule would run afoul of the *eBay* Court's holding that categorical rules are inconsistent with "traditional equitable principles." *eBay*, 126 S. Ct. at 1840-41.

loss of current or future market share, as a result of continuing sales of Medtronic's products, ACS's market evidence is totally inadequate to justify a permanent injunction.

b. ACS's Alternative Theories Of Irreparable Harm Are Also Unsupported And Unconvincing

ACS speculates (with little supporting evidence) that its past loss of sales to Medtronic caused irreparable injury by: **REDACTED** and (3) "damaging" ACS's "goodwill" "in the eyes of investors." (D.I. 727 at 8-9, 16-17.) Because each of these arguments rests on vague, unsupported allegations of past harm, and because ACS has failed to provide any evidence that it will continue to suffer these alleged injuries absent an injunction, each of these highly speculative arguments must be rejected.

ACS's argument that Medtronic's stents caused irreparable harm by REDACTED REDACTED is without merit. The only "supporting evidence" ACS offers shows, at best,

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Moreover, this Court has indicated, in rejecting a REDACTED in a post-*eBay* permanent injunction case, that lost "opportunities" to conduct research are likely compensable by money damages. *See Praxair*, 479 F. Supp. 2d at 444 n.6 (rejecting the patent holders' claim that money damages are not sufficient to compensate for lost "opportunities" to conduct research due to budgetary constraints allegedly caused by the defendant's infringement). As the Federal Circuit has recognized, accepting the argument that lost opportunities to conduct research and

development causes irreparable harm would permit any patent holder with a research and development program to enjoin an infringer:

> If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief. Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits. For that reason, adopting the principle that Lilly proposes would "disserve the patent system."

Eli Lilly & Co. v. Am. Cyanamid Co., 82 F.3d 1568, 1578 (Fed. Cir. 1996) (citation omitted).

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Once again, ACS's only evidence in support of this theory at best shows *past* harm. (*See* D.I. 726 Ex. 7.) ACS has not provided any evidence that Medtronic's alleged infringement

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Finally, ACS's unsupported claim that its past loss of market share "damaged the goodwill of ACS's business in the eyes of investors" also is unavailing. ACS does not explain the meaning of "goodwill in the eyes of investors" and fails to cite to any court that has granted permanent injunctive relief based on such a theory. ACS bases its argument on a conclusory statement by its own employee, Mr. Pacitti. (*See* D.I. 729 ¶ 10.) Yet Mr. Pacitti does not explain any causal connection between the market share of one product among many in ACS's portfolio and its public share price. Nor does he cite any data or testimony by specific investors.

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12 An even more fundamental defect is that neither Mr. Pacitti's declaration nor his deposition testimony demonstrate that he has personal knowledge regarding "the goodwill of ACS's business in the eyes of investors." (D.I. 729 ¶ 10.) Consequently, Mr. Pacitti's unsupported

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3. ACS's Licensing Of The Lau Patents To Its Competitors Demonstrates That It Will Not Suffer Irreparable Harm Absent An Injunction

The fact that ACS has granted licenses to the two dominant competitors in the stent market – Boston Scientific and Cordis – is wholly inconsistent with ACS's claim of irreparable harm. A "[p]laintiff's willingness to forego its patent rights for compensation . . . is one factor to consider with respect to whether plaintiff will suffer irreparable harm." *IMX*, 469 F. Supp. 2d at 225 (denying a motion for a permanent injunction where the patent holder had licensed its patent on two occasions).[13]

This Court has recognized, in denying a preliminary injunction in another stent case, that stent manufacturers are not suffering irreparable harm as a result of their competitors' alleged infringement because of the common practice of cross-licensing each other's intellectual property. *See Scimed Life Sys., Inc. v. Johnson & Johnson*, No. 00-404, 2001 WL 652027, at *1 (D. Del. Mar. 29, 2001) ("Having multiple patent cases on her docket relating to various stents manufactured by the same group of litigants, the court is not inclined to enter injunctive relief on a preliminary basis in this or any similar case, given . . . the fact that licenses have been granted under various of these patents, *i.e.*, *there is no irreparable harm*.") (emphasis added).

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opinions of ACS's goodwill in the eyes of investors are inadmissible and should be disregarded. *See* Fed. R. Evid. 602.

[13] Although the *eBay* Court rejected the categorical rule that a "'plaintiff's willingness to license its patents' . . . would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue[,]" 126 S. Ct. at 1840-41, since *eBay*, courts (including this Court) have continued to view a patent holder's willingness to license its patent rights as an important factor weighing against a finding of irreparable harm. *See, e.g.*, *IMX*, 469 F. Supp. 2d at 225; *MercExchange*, 500 F. Supp. 2d at 570-71; *Sundance*, 2007 U.S. Dist. LEXIS 158, at *9.

In another coronary medical device case, this Court similarly found that the patent holder "d[id] not present a very compelling case of irreparable harm" where it had licensed two direct competitors that "substantially comprise[d] the remainder of the [relevant] market." *Cordis Corp. v. Adv. Cardiovascular Sys., Inc.*, No. 97-635, 1999 U.S. Dist. LEXIS 15529, at *23-*24 (D. Del. Sept. 10, 1999); *see also Am. Cyanamid*, 833 F. Supp. at 119, 132 (denying a preliminary injunction where the plaintiff had granted its largest competitor a license to use the patent-in-suit pursuant to a settlement and cross-licensing agreement, thereby "licens[ing] away [the patent holder's] right to be the sole supplier of synthetic absorbable sutures."). Indeed, licensing a competitor is "incompatible" with a patent holder's "right to exclude." *T.J. Smith & Nephew Ltd. v. Consol. Med. Equip., Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1987).

Cordis and Boston Scientific have used their licenses to ACS's Lau patents as the platform for their very successful drug-eluting stents (*see* D.I. 727 at 10), which ACS admits now "dominate" the stent market. (*Id*. at 11.) Thus, by licensing Cordis and Boston Scientific, not only has ACS voluntarily given up its right to exclusively market products covered by the patents-in-suit, but it has enabled these competitors to dominate the stent market at the expense of ACS (and Medtronic). It is simply not credible for ACS to claim that it will suffer irreparable harm absent an injunction against Medtronic's stents under these circumstances.

ACS's history of voluntarily licensing the Lau patents to competitors,

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also demonstrates that any injury resulting from Medtronic's purported infringement is compensable by money damages. *See IMX*, 469 F. Supp. 2d at 225 n.24 ("[L]icensing activities . . . suggest that plaintiff's injury would be compensable in damages."); *see also Sundance*, 2007 U.S. Dist. LEXIS 158, at *9 (the fact that

the patent holder licensed others to use the patent-in-suit demonstrated that money damages were adequate); *Arthrex*, 2002 U.S. Dist. LEXIS 7634, at *13 ("[T]he act of licensing suggests that any injury suffered by the patentee is compensable in money damages, obviating the claim for injunctive relief."); *cf. Illinois Tool Works, Inc. v. Grip-Pak, Inc*., 906 F.2d 679, 683 (Fed. Cir. 1990) (affirming the lower court's denial of a preliminary injunction, in part, because the patent holder had licensed its patent to another, meaning that the patent holder "does not have the exclusive market for [the patented product], and the court can place a value on the market for those [products] by looking at the licenses themselves.").

ACS argues that the Court should ignore its history of licensing the Lau patents because it purportedly has a policy against licensing those specific patents "for money alone" and has only granted licenses to the Lau patents in the context of settlements and cross-licenses. (D.I. 727 at 9-10, 22.) This claim, even if true, is legally irrelevant. *See IMX*, 469 F. Supp. 2d at 225 (denying a request for a permanent injunction where the patent holder had licensed its patent on two occasions, one of which stemmed from a settlement with a competitor); *Cordis*, 1999 U.S. Dist. LEXIS 15529, at *23-*24 ("[T]he fact that the two licenses involve more than monetary compensation is less than compelling when the licensees substantially comprise the remainder of the OTW market."); *Am. Cyanamid*, 833 F. Supp. at 132 (denying a preliminary injunction where the patent holder had licensed the patent-in-suit to its largest competitor pursuant to a settlement and cross-licensing agreement).

The context or collateral provisions of ACS's licensing activity does not change the fact that ACS has, on multiple occasions, sacrificed its right to exclude others from practicing its patent rights in exchange for some form of compensation. Such conduct is simply inconsistent with its claim that it will be irreparably harmed absent an injunction against Medtronic's stents.

4. ACS's Delay In Seeking Injunctive Relief And Prosecuting This Litigation Weighs Against A Finding Of Irreparable Harm

Although ACS now contends that it suffered irreparable harm as a result of the accused products as far back as December 1997 (*see* D.I. 727 at 5, 15), it did not even attempt to seek a preliminary injunction. In fact, ACS waited nearly ten years – and post judgment – to request any form of injunctive relief. ACS's delay is yet another factor militating against any claim of irreparable harm. *See MercExchange*, 500 F. Supp.2d at 573 (determining that the patent holder's failure to seek a preliminary injunction in a six-year-old patent litigation weighed against a finding of irreparable harm); *Sundance*, 2007 U.S. Dist. LEXIS 158, at *7 (considering the patent holder's delay in seeking injunctive relief in denying a permanent injunction); *see also PGBA, LLC v. United States*, 389 F. 3d 1219, 1229-31 (Fed. Cir. 2004) (finding no abuse of discretion where the lower court considered the plaintiff's failure to seek a preliminary injunction as a factor weighing against a permanent injunction); *cf. T.J. Smith & Nephew*, 821 F.2d at 648 (recognizing that "delay in seeking an injunction" is "incompatible with . . . the right to exclude").

Although ACS's complaints listed permanent and preliminary injunctive relief among the remedies it was seeking (*see* CA No. 98-314 (SLR), D.I. 1 at 5; CA No. 98-80 (SLR), D.I. 269 at 6; D.I. 312 at 6), it never attempted to enjoin Medtronic's accused devices in the seven years prior to the jury trial. In fact, not only did ACS fail to seek a preliminary injunction, but it has repeatedly sought to delay the resolution of the case, agreeing to a two-year stay of the action in 2000 (*see* D.I. 245) and twice requesting a stay of the action pending arbitration. (*See* D.I. 37, 371.) Then, following the trial, after ACS had received a verdict on infringement, it still chose to wait more than two years, and months after the Court's post-trial rulings, to seek an injunction.

It is simply not credible for ACS now to claim that it will suffer irreparable harm absent an injunction (1) where ACS failed to seek a preliminary injunction against these same stents in 1998 when Medtronic's stents had 45% of the overall market and purportedly had caused ACS's market share to "tumble" from 64% to 39%, and (2) where ACS sought to delay rather than expedite the litigation. (*See* D.I. 727 at 5-6.) As the trial court in *eBay* observed on remand, "if [the patent holder's] true goal was to defend its right to exclude, it would likely have at least *attempted* to stop [the defendant] . . . from further improving its foothold on the market during the lengthy litigation period." 500 F. Supp.2d at 573.

Equitable relief is especially inappropriate here because ACS has used the delay in seeking an injunction to its competitive advantage. ACS's Injunction Motion is a transparent attempt to leverage its success (to date) in this litigation to gain a competitive advantage against Medtronic with respect to the parties' competing drug-eluting stents. ACS filed its motion, which also sought relief against Medtronic's soon-to-be released drug-eluting stent Endeavor, on the eve of Medtronic's announcement of the successful results of its late-stage clinical trial for Endeavor (which will ultimately lead to FDA approval of the device).[14] (D.I. 752 ¶ 5 & Ex. A.)

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[14] As yet another example of ACS's anticompetitive use of the Injunction Motion, ACS apparently "leaked" news of the Injunction Motion to Morgan Stanley on Friday, June 29, 2007 *before* it was filed with the Court in an obvious attempt to adversely affect Medtronic's share price or otherwise harm Medtronic. Although the Injunction Motion was not filed with the Court until after business hours on Friday evening, June 29, 2007 (D.I. 734 ¶¶ 6-7 & Exs. A-B), Morgan Stanley published a report commenting on the Injunction Motion that Sunday, July 1, 2007. (*See* Louden Decl. Ex. G.) The report, entitled "Noose Tightening on Medtronic," speculated that the Injunction Motion "could hamper Medtronic's efforts to enter the U.S. DES market." (*Id.*) ACS has not denied that it facilitated Morgan Stanley's quick response to the Injunction Motion by leaking news of it prior to its filing with the Court. Moreover, ACS has blocked Medtronic's legitimate discovery efforts regarding how and why the Injunction Motion was leaked to Morgan Stanley by refusing to produce documents, or to designate a corporate representative to answer questions, relating to this

[Footnote continued on next page]

Courts have made clear that the timing of an injunction motion for competitive advantage strongly weighs against such relief. *Cf. Century Time, Ltd. v. Interchron, Ltd*., 729 F. Supp. 366, 368 (S.D.N.Y. 1990) (finding that delay in seeking an injunction calculated to gain a tactical advantage against a competitor barred injunctive relief because "[w]e simply cannot tolerate tactical maneuvering, in injunction matters, whereby parties sit back and wait for what they believe to be timing most injurious to the procedural fairness for their adversaries.").

5. The Uncertainty Surrounding (A) The Court's Claim Construction And (B) The Validity Of The Lau Patents Weighs Against A Finding Of Irreparable Harm

A finding of irreparable harm to ACS is especially inappropriate at this stage of the litigation in light of the uncertainty surrounding the outcome of the case on appeal, as well as the validity of the patents themselves. In fact, these factors point to a high likelihood of *irreparable harm to Medtronic* if an injunction is improvidently granted.

a. The Uncertainty Of The Claim Construction Means Uncertainty Regarding Both Infringement And Validity Of The Lau Patents

This Court has recognized that a permanent injunction may not be appropriate prior to the conclusion of the appeal process where "the judge has determined that the question of infringement is a close one." *IMX*, No. 03-1067, D.I. 306 at 2-3 (D. Del. Apr. 25, 2007) (attached as Louden Decl. Ex. D).

[Footnote continued from previous page]

matter. (*See* Louden Decl. Ex. H.) Ironically, ACS has accused another stent manufacturer of similar misconduct in another patent infringement case pending before this Court. In *Abbott Labs. v. Johnson & Johnson*, C.A. No. 06-613, ACS accused Johnson & Johnson of "broadcast[ing] threatening statements to industry analysts regarding alleged infringement" "to cast a cloud over the launch of [ACS's yet-to-be released drug-eluting stent] Xience V." (C.A. No. 06-613, D.I. 1 (D. Del. Sept. 29, 2006) at ¶¶ 19, 21) (attached as Louden Decl. Ex. I).)

In this case, the Court specifically recognized that the claim construction decisions prior to and during trial were a close call. Indeed, the Court originally adopted Medtronic's proposed construction, construing "undulating pattern" and "undulating portion" to mean "a wavelike pattern that includes any *combination of U-shaped, W-shaped, or Y-shaped members*." (D.I. 542 at 5 (emphasis added).) It is beyond dispute that the accused Medtronic stents do not possess such a "combination" of shaped members. During the jury trial, however, the Court changed the construction of "undulating pattern" and "undulating portions" to mean simply "a wavelike pattern," thereby materially broadening the scope of the claims. (D.I. 615.)

In between these two different constructions, the Court twice modified its constructions of related claim terms, including the construction of "cylindrical elements," which incorporates the phrase "undulating pattern." (D.I. 579; D.I. 580 at 7:10-11; D.I. 587.) Later, the Court withdrew its construction of "cylindrical elements" and determined that it would interpret the phrase "at the conclusion of the evidence for purposes of instructing the jury." (D.I. 587.)

Medtronic objected to these changes, and the Court noted that Medtronic's position "well could be" the correct one:

> I have to admit, I think both parties stated absolutely appropriate constructions in this case. I just felt it was more important for me under the latest iteration of what the Federal Circuit looks at to make the claim language consistent rather than trying to make the specification, prosecution history consistent with the claim language. So that's where I went, but good argument. We'll let the Federal Circuit – what can I say? I don't have a clue which way the Federal Circuit will go on this. I wish I did.

(D.I. 637 at 1711:8-19 (attached as Louden Decl. Ex. J).) Five months after the jury trial here, the Federal Circuit issued its *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006), which emphasized that claim terms must be construed in light of the invention described in the specification.

In addition to advancing claim constructions that broadened the scope of the claims for infringement purposes, ACS also advocated, and obtained, certain claim constructions that narrowed the scope of the claims for validity purposes. For example, ACS argued that the "cylindrical elements" limitation should be confined to cylindrical rings that "are not, in and of themselves, stents," in an effort to avoid the application, *inter alia*, of Medtronic's prior art Boneau patents. (D.I. 542 at 3; *see also* D.I. 470 at 10-12.) Thus, any further modifications by the Federal Circuit to this Court's claim constructions could have a direct impact on the findings of infringement or validity (or both) of the Lau patents.

Medtronic respectfully submits that in view of the great uncertainty surrounding the various claim constructions in this case, and in view of the grave and irreversible consequences of a permanent injunction (*see* Part IV.B & C, *infra*), ACS's motion is premature at best. As the Court is undoubtedly aware, the Federal Circuit is reported to have an unusually high reversal rate of district court claim constructions – approximately 40%.[15] Consequently, because the parties' competing claim constructions are a "close" call, and because the entire outcome of the case could change if the Federal Circuit adopts different constructions (such as the Court's

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[15] *See* Andrew T. Zidel, *Patent Claim Construction in the Trial Courts: A Study Showing the Need for Clear Guidance from the Federal Circuit*, 33 SETON HALL L. REV. 711, 745–46 (2003) (41.5% of the 94 claim construction decisions by the Federal Circuit in 2001 were reversals, either in whole or in part); Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 BERKELEY TECH. L.J. 1075, 1104 (2001) (44% of the 179 district court claim constructions appealed to the Federal Circuit between January 1, 1998 and April 30, 2000 were modified on appeal); Gretchen A. Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time is Ripe for a Consistent Claim Construction Methodology*, 8 J. INTELL. PROP. L. 175, 206–07 (2001) (40% of the 160 claim constructions appealed to the Federal Circuit after the *Markman* decision in 1996 through 2000 were modified on appeal).

original construction of "undulating pattern"), this Court should reject ACS's Injunction Motion. (*See* D.I. 717.)

b. The Pending Reexamination Of The Lau Patents In The PTO Also Casts Doubt On The Validity Of The Lau Patents

The Lau patents are now the subject of reexamination proceedings, and the United States Patent & Trademark Office ("PTO") has preliminarily rejected all of the adjudicated claims of all four patents. (*See* Louden Decl. Ex. K at 3, 15, 26, 50.) In *eBay*, Justice Kennedy recognized in his concurrence that "[t]he potential vagueness and suspect validity of some . . . patents may affect the calculus under the four-factor test." 126 S. Ct. at 1842. On remand, the fact that the PTO twice had rejected the claims of one of the patents-in-suit (which was the subject of pending reexamination hearings) weighed against a finding of irreparable harm. *MercExchange*, 500 F. Supp. 2d at 574-75. The *eBay* court recognized that when considering "a *prospective* motion in equity, it would be imprudent not to consider ongoing reexamination." *Id*. at 575 n.15 (emphasis in original).

Such consideration is especially important now that the Supreme Court has lowered the bar for invalidity by eliminating the "teaching, suggestion or motivation" test as a prerequisite to a finding of obviousness. *See KSR Int'l Co. v. Teleflex, Inc*., 127 S. Ct. 1727, 1741 (2007). The *KSR* holding is significant here because in December 2006 the PTO rejected all of the adjudicated claims of the Lau patents as either anticipated or obvious in a non-final office action. (*See* Louden Decl. Ex. K at 3, 15, 26, 50.) ACS filed its responses to the non-final office action on March 21, 2007, and the matter is currently under submission with the PTO. (Louden Decl. Ex. L.) *KSR* significantly increases the likelihood that the PTO ultimately will find the asserted claims of the Lau patents to be obvious, in light of the multiple prior art references that are currently under consideration.

In view of the uncertainty surrounding the outcome of this case on appeal and the outcome of the ongoing PTO reexamination, a permanent injunction is unwarranted.

B. The Public Interest Would Be Disserved By A Permanent Injunction Against Medtronic's Lifesaving Bare-Metal Stents

Enjoining sales of Medtronic's stents would: (1) deprive patients of lifesaving devices with unique safety and efficacy advantages over other stents, and (2) harm competition in the vital bare-metal stent market at a time when demand is increasing and the number of manufacturers is decreasing.

1. An Injunction Would Injure The Public Health

"[F]or good reason, courts have refused to permanently enjoin activities that would injure the public health." *Cordis Corp. v. Boston Scientific Corp.*, 99 Fed. Appx. 928, 935 (Fed. Cir. May 28, 2004); *see also Scripps Clinic & Research Found. v. Genetech, Inc*., 666 F. Supp. 1379, 1401 (N.D. Cal. 1987) (finding that the possibility that the accused product would eliminate safety risks present in other products counseled against granting a preliminary injunction against the product).

a. Medtronic's Bare-Metal Stents Have Design And Application Advantages Over The Currently Available Bare-Metal And Drug-Eluting Stents

Stents are a vital tool in the treatment of coronary artery disease. (Pearle Decl. ¶ 8.) The use of stents in angioplasty procedures has nearly eliminated acute vessel closure and reduced restenosis rates (or re-closure of the artery following implantation) by more than 50% percent. (*Id*.) Although drug-eluting stents have replaced bare-metal stents as the most commonly used stent, serious questions have arisen about the safety of drug-eluting stents and the high cost of these newer devices. (*Id*. ¶¶ 14-19.)

Recent studies have shown that there are serious safety concerns with the currently available drug-eluting stents (manufactured by Cordis and Boston Scientific) that are not present with bare-metal stents like those from Medtronic. These studies have found that Cordis' Cypher and Boston Scientific's Taxus are associated with a higher risk of late stent thrombosis, myocardial infarction (heart attack), and death as compared with bare-metal stents.[16] (Pearle Decl. ¶ 15.)

In view of these safety concerns, most cardiologists (including ACS's own expert, Dr. Kahn) recommend that drug-eluting stent patients use aspirin indefinitely and a second anti-clotting agent (such as Plavix) for at least one year after implantation to prevent thrombosis. (Kahn Dep. at 52:20-53:22 (attached as Louden Decl. Ex. B); (Pearle Decl. ¶ 16).) The prolonged use of anticlotting agents presents its own risks, such as an increased risk for serious bleeding. (Pearle Decl. ¶ 17; Kahn Dep. at 53:23-54:15 (attached as Louden Decl. Ex. B).) This means that drug-eluting stents are not appropriate for patients with a high risk of bleeding and with the need for further surgeries. (Pearle Decl. ¶ 17.)

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[16] *See, e.g.*, Bo Lagerqvist, et al., *Long-Term Outcomes with Drug-Eluting Stents Versus Bare-Metal Stents in Sweden*, 356 N. ENG. J. MED. 1009 (2007) (finding that drug-eluting stents were associated with an increased rate of death as compared with bare-metal stents); Gregg W. Stone, et al., *Safety and Efficacy of Sirolimus and Paclitaxel-Eluting Coronary Stents*, 356 N. ENGL. J. MED. 998 (2007) (finding that stent thrombosis was more common in drug-eluting stents than bare-metal stents after one year of implantation); Matthias Pfisterer, et al., *Late Clinical Events After Clopidogrel Discontinuation May Limit the Benefit of Drug-Eluting Stents*, 48 J. AM. COLL. CARDIOL. 2584 (2006) (reporting that documented cases of late stent thrombosis and related death/target myocardial infarction (heart attack) were twice as frequent after implantation of drug-eluting stents versus bare-metal stents); Edoardo Camenzind, *Safety of Drug-Eluting Stents: Insights from Meta Analysis*, Presented at the European Society of Cardiology 2006 World Congress, Barcelona (Sept. 2-6, 2006) (finding that drug-eluting stents carry a greater risk of myocardial infarction (heart attack) than bare-metal stents) (collectively attached as Pearle Decl. Ex. E.)

Moreover, in light of the high cost of drug-eluting stents (which are typically two-and-a-half times more expensive than bare-metal stents (Kahn Dep. at 55:25-56:6 (attached as Louden Decl. Ex. B)), studies have shown that, with the exception of patients with a high risk for restenosis, bare-metal stents remain the most cost-effective stent devices on the market. *See, e.g.*, Mark J. Eisenberg, *Drug-Eluting Stents: The Price Is Not Right*, 114 CIRCULATION 1745, 1751 (2006) ("At current prices, using DES in an across-the-board manner is not the optimal strategy from a cost-effectiveness point of view.") (attached as Pearle Decl. Ex. F). The high cost of drug-eluting stents is amplified by the fact that the anticlotting medications that are now recommended for drug-eluting stent patients are quite expensive. (Pearle Decl. ¶ 20.)

In light of the foregoing, experts generally agree that bare-metal stents such as Medtronic's will continue to be one of the safer and more suitable stent choices for patient populations: (1) with a relatively low risk of restenosis; (2) at a high risk of bleeding; (3) with the need for further surgeries; or (4) for whom the costs of anticlotting medications are problematic. (*Id*. at ¶ 17; Declaration of Dr. Thaddeus Tolleson ("Tolleson Decl.") ¶ 5.)

Along with posing a lower risk of late stent thrombosis (and being more cost-effective) than the currently available drug-eluting stents, Medtronic's bare-metal stents also have several design advantages over the bare-metal stents of Medtronic's two competitors, ACS and Boston Scientific.[17] Many cardiologists prefer Medtronic's bare-metal stents because of their modular design and rounded struts, which result in increased deliverability and conformability. (Declaration of Dr. Rodney Badger ("Badger Decl.") ¶¶ 4, 6; Tolleson Decl. ¶¶ 3-4; Pearle Decl. ¶ 10-11.) Medtronic's modular stents travel smoothly through the most tortuous of coronary

[17] Cordis/Johnson & Johnson no longer sells bare-metal stents in the United States. (Kahn Dep. at 4:22-5:15) (attached as Louden Decl. Ex. B).)

arteries. (Badger Decl. ¶ 4; Tolleson Decl. ¶ 4; Pearle Decl. ¶ 10.) ACS's and Boston Scientific's stents, on the other hand, tend to scrape against the wall of blood vessels with their square, laser-cut struts, making them less deliverable. (Badger Decl. ¶¶ 4, 7; Pearle Decl. ¶ 11.) At least one study has found that bare-metal stents with more flexible designs (such as Medtronic's) may cause less vascular injury than stents with rigid struts, which may result in lower restenosis rates. Caitríona Lally, *Cardiovascular Stent Design and Vessel Stress: A Finite Element Analysis*, 38 J. BIOMECHANICS 1574, 1575, 1579 (2005) (using a computer-based analysis to predict that Medtronic's modular S7 would cause less vascular injury than Boston Scientific's NIR slotted tube laser-cut stent because of the greater conformability of the S7) (attached as Pearle Decl. Ex. B); (*see also* Pearle Decl. ¶ 10; Declaration of Jeff Allen ("Allen Decl.") ¶ 4; Badger Decl. ¶ 7).

Another characteristic that distinguishes Medtronic's Driver and MicroDriver stents is the fact that they are constructed with an advanced cobalt-chromium alloy that is stronger and denser than the stainless steel used in competing bare-metal stents (such as Boston Scientific's). (Declaration of Dr. Douglas Ebersole ("Ebersole Decl.") ¶ 8; Allen Decl. ¶ 4.) This stronger and denser material permits Driver to have thinner struts, resulting in increased flexibility and deliverability. (Ebersole Decl. ¶ 8; Allen Decl. ¶ 4.) Indeed, ACS's declarant, Dr. Kahn, acknowledged that cobalt-chromium stents (like Driver and MicroDriver) have thinner struts with increased flexibility that may be more deliverable in patients with particularly tortuous arteries.[18] (Kahn Dep. at 43:13-45:17 (attached as Louden Decl. Ex. B).)

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[18] Although ACS's Vision and Mini Vision are also made of cobalt-chromium, an injunction against Medtronic's stents would leave only one family of cobalt-chromium stents on the U.S. market.

Medtronic's Driver also provides superior support for the vessel wall because its scaffolding has the smallest unsupported cell area of any currently available bare-metal stent (including ACS's). (Allen Decl. ¶ 3 & Ex A at MDTI 09745.)

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Tissue prolapse also has been associated with restenosis. *See* Patrick J. Prendergast, *Analysis of Prolapse in Cardiovascular Stents: A Constitutive Equation for Vascular Tissue and Finite Element Modeling*, 125 J. BIOMED. ENG'G 692, 693 (2003) (noting that "several clinical studies have associated prolapse with the appearance of restenosis.") (attached as Louden Decl. Ex. M).

ACS can hardly dispute that Medtronic's bare-metal stents have design advantages preferred by many doctors. Indeed,

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In addition to the advantages that Medtronic's stent platform provide, these stents also are the only devices available with Medtronic's proprietary MX2 delivery system. (Ebersole Decl. ¶ 9.) Unlike the RX delivery system used with ACS's and Boston Scientific's bare-metal stents, the MX2 delivery system permits cardiologists to change guidewires during an angioplasty procedure without having to remove the entire platform. (*Id*.) This is a particularly important advantage in patients with tortuous lesions because it is often difficult to maneuver the wire through these patients' blood vessels, and a change of guidewires is sometimes necessary. (*Id*.) By contrast, if a guidewire has to be replaced during a procedure using the RX system, the entire

stent platform must be re-inserted, prolonging the length of the procedure and increasing the likelihood of complications, such as re-closure of the vessel, and thus lowering the success rate of the procedure. (*Id.*)

b. Medtronic's Bare-Metal Stents Are Preferred By Doctors Throughout the United States

In view of the foregoing safety and efficacy advantages, many doctors throughout the United States prefer Medtronic's stents over its competitors.

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Indeed, ACS's own paid expert, Dr. Kahn, acknowledged that some of his colleagues prefer Medtronic's Driver stent. (Kahn Dep. at 57:16-58:1 (attached as Louden Decl. Ex. B).)

In addition, four leading interventional cardiologists from locations throughout the country (including Washington, D.C., Lakeland, Florida, Tyler, Texas, and Provo, Utah), each of whom has implanted thousands of stents over their careers, have submitted declarations in opposition to ACS's Injunction Motion. (*See* Badger Decl.; Ebersole Decl.; Pearle Decl.; Tolleson Decl.) Each of these doctors believes that an injunction against Medtronic's bare-metal stents would have a deleterious effect on the public health.[19] (*See* Badger Decl. ¶¶ 9-10;

[19] It is notable that whereas ACS submitted a declaration from one doctor (Dr. Kahn), who practices in one discrete part of the country (the greater Detroit area), claiming that physicians and patients will not be harmed if Medtronic's bare-metal stents are enjoined (D.I.

[Footnote continued on next page]

Ebersole Decl. ¶ 10; Tolleson Decl. ¶ 6; Pearle Decl. ¶ 21.) Those patients with the most tortuous arteries, whose conditions require a highly deliverable Medtronic stent, may be forced to undergo riskier and more invasive procedures (such as coronary bypass surgery) to treat their heart disease.[20] (*See* Badger Decl. ¶ 9-10; Ebersole Decl. ¶ 10; Tolleson Decl. ¶ 6.) Thus, an injunction against Medtronic's bare-metal stents would deprive patients with narrowed arteries of the stent most suited for their condition, and it would deprive physicians of the stent they prefer for certain types of patients.

Courts have made clear that an injunction in these circumstances would disserve the public interest. *See Cordis*, 99 Fed. Appx. at 935-36 (affirming the district court's determination that the public interest weighed against a preliminary injunction because "the record contain[ed] evidence that some doctors preferred the Taxus stent over the Cypher stent."); *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) (holding that the trial court did not err in finding that the public interest would be harmed by the grant of a preliminary injunction because the defendant's device (an intraaortic balloon catheter) was preferred by some doctors over the patent holder's device); *Am. Cyanamid*, 833 F. Supp. at 134 ("'[T]he public will be harmed by an

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730 ¶ 6-7.), Medtronic has submitted declarations from four doctors from locations throughout the country who believe that an injunction will seriously harm public health.

[20] Dr. Rodney Badger, a high volume interventional cardiologist at the Central Utah Medical Clinic in Provo, Utah, has provided a clinical example of the type of patient who would be adversely affected by an injunction against Medtronic's bare-metal stents. On REDACTED, Dr. Badger treated a REDACTED man REDACTED suffering from acute coronary syndrome. After attempting to deliver several other drug-eluting and bare-metal stents, Dr. Badger successfully deployed a Medtronic MicroDriver stent into the patient's lesion with an excellent clinical outcome. Without the availability of the MicroDriver, this patient would have required coronary bypass graft surgery, which would have presented a very high risk of complications in light of this patient's weight. (Badger Decl. ¶ 10.)

injunction [if] some physicians prefer' the accused medical or surgical product.") (citation omitted) (second alteration in the original).

2. An Injunction Would Damage The Public's Interest In A Competitive Stent Market

An injunction also would be improper here given the strong public interest in competition in the stent market. The Federal Circuit explained, in resolving an injunction motion in a stent case before this Court, that "a strong public interest supports a broad choice of drug-eluting stents, even [where] no published study proves the superiority [of one drug-eluting stent over the other]." *Cordis*, 99 Fed. Appx. at 935; *see also Cordis Corp. v. Boston Scientific Corp.*, No. 03-027, 2003 U.S. Dist. LEXIS 21338, at *6 (D. Del. Nov. 21, 2003) (noting the "obvious concern of depriving the public of the best and safest medical devices by limiting competition"); *Am. Cyanamid Co.*, 833 F. Supp. at 125 (recognizing that "[i]ncreased competition in the marketplace is in the public interest," where the market for suture products had been dominated for years by two competitors who had cross-licensed their products). Indeed, plaintiff Abbott Laboratories itself has recognized the "social benefit of . . . competition in [the vascular intervention] market" in another case. (*See Johnson & Johnson v. Guidant Corp.*, No. 06-7685, D.I. 18 at 20 (S.D.N.Y. Nov. 15, 2006) (attached as Louden Decl. Ex. P).)

Competition in the bare-metal stent market is now more important than ever in light of the above-mentioned safety concerns regarding the currently available drug-eluting stents. Because of those concerns and the high costs associated with these new devices, many cardiologists are turning back to the more reliable bare-metal stents. (*See* Tolleson Decl. ¶ 5; Pearle Decl. ¶ 19; Ebersole Decl. ¶ 6; Kahn Dep. at 51:11-25 (attached as Louden Decl. Ex. B).)

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Compounding the importance of competition in the bare-metal stent market is the fact that, as noted above, Cordis no longer manufactures bare-metal stents, which has reduced the number of major stent manufacturers other than Medtronic from three to two. (Kahn Dep. at 4:22-5:15; 81:2-8 (attached as Louden Decl. Ex. B).) An injunction would further reduce the number to just two – ACS and Boston Scientific, who are known to be close collaborators.[21]

Competition in the market is also critical to public safety because of the ever-present risk of product recalls, the consequences of which are potentially devastating. ACS's Multi-Link Vision and Multi-Link Zeta bare-metal stents were the subject of three separate product recalls in

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[21] Not only did Abbott collaborate with Boston Scientific in its acquisition of Guidant (by acquiring Guidant's cardiovascular business) (Louden Decl. Ex. Q at 60), but to facilitate that transaction, Abbott acquired 64.6 million shares of Boston Scientific common stock directly from Boston Scientific and loaned $900 million to a wholly owned subsidiary of Boston Scientific at a below-market interest rate of 4 percent. (*Id.*) As a further part of that transaction, Abbott has promised to manufacture for Boston Scientific a private label version of its new drug-eluting stent, Xience. (Louden Decl. Ex. R ¶¶ 5-9.) Boston Scientific's private label brand of the Xience stent is called Promus and is identical in all respects to Xience. (Louden Decl. Ex. R ¶¶ 7, 13.)

2003 in the United States and abroad. (*See* Pearle Decl. ¶ 12 & Ex C.) Additionally, Boston Scientific's bare-metal stents have been the subject of at least two FDA "Class I" recalls in 1998 and 2004. (*See* Pearle Decl. ¶ 12 Ex D.) In the event that one or more bare-metal stents from ACS or Boston Scientific were the subject of a recall, an injunction against Medtronic would deprive patients of a potentially lifesaving alternative. (Pearle Decl. ¶ 12.) Indeed, ACS's own paid expert, Dr. Kahn, conceded that a major recall of ACS's and Boston Scientific's stent product line would be detrimental to patients if there were no Medtronic stent available. (Kahn Dep. at 59:4-11 (attached as Louden Decl. Ex. B).)

ACS also has not established that it can meet the increased demand if Medtronic's stents are enjoined. (*See* D.I. 727 at 12.) The fact that ACS allegedly sold a large number of bare-metal stents (892,000) five years ago is irrelevant without evidence that ACS *currently* (or in the future) has the ability to increase its manufacturing, distribution, and selling capacity. Indeed, rather than leave its excess capacity idle, ACS surely diverted and/or eliminated this excess capacity when the demand for bare-metal stents decreased. At a minimum, ACS has not established otherwise.

In addition,

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Thus, because ACS's evidence fails to show that ACS presently (or in the future) can meet the increasing demand for bare-metal stents, the public interest in a competitive and amply-supplied stent market strongly weighs against an injunction. *See Cordis*, 2003 U.S. Dist. LEXIS 21338, at *6 (denying Cordis' request for a preliminary

injunction against Boston Scientific's drug-eluting stent because, "[a]side from the obvious concern of depriving the public of the best and safest medical devices by limiting competition, it is apparent from the evidence that Cordis cannot ensure an adequate supply of drug-eluting stents to meet current market demand.").

3. The Public Interest Is Not Served By Enforcing A Verdict Based On A Questionable Claim Construction And On Patents Of Questionable Validity

ACS argues that the public interest weighs in favor of an injunction because "the public interest is best served by enforcing patents." (D.I. 727 at 24.) But the public's interest in enforcing patent rights is much less compelling in this case. As noted above (Part IV.A.5), the PTO has preliminarily rejected the adjudicated claims of all four patents, *and* this Court has expressed concern about claim constructions that led to findings of infringement and validity. *See MercExchange*, 500 F. Supp. 2d at 586 ("[T]he court deems it proper to consider the nature of the patent, as well as repeated indications from the PTO that such patent is invalid as obvious, when considering the public's interest in protecting the patent holder through injunctive relief."); *see also* 4 John Gladstone Mills III, *et al*., Patent Law Fundamentals § 20.65 (updated May 2007) (according to *eBay*, "if there appears to be a chance that the patent may be invalid, then the public interest is best served by denying an injunctive remedy.") (emphasis added).

C. The Balance Of The Hardships Overwhelmingly Weighs Against An Injunction

Whereas the harm ACS claims to have suffered primarily occurred in the past and is readily compensable by money damages,

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for the company, and given that bare-metal stents are the Coronary and Peripheral Division's main product line on the United States market,

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[22] In anticipation of the great harm that will befall Medtronic Vascular's business if an injunction issues, ACS relies heavily on the Federal Circuit's statement that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurfing Int'l Inc. v. AMF, Inc*., 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986). But the Federal Circuit subsequently warned that "*Windsurfing* does not overcome the equities of a case," "[n]or can *Windsurfing* be applied mechanically." *Standard Havens Prods., Inc. v. Gencor Indus., Inc*., 897 F.2d 511, 515 (Fed. Cir. 1990). Indeed, a rule that the defendant's infringement alone is enough to outweigh any harm to the defendant resulting from an injunction would eviscerate the balance of the hardships prong and directly conflict with the *eBay* Court's rejection of categorical rules favoring an injunction. Moreover, since *eBay*, several courts have considered the potential harm to an alleged infringer's business as an important factor weighing against a permanent injunction. *See, e.g.*, *Sundance*, 2007 U.S. Dist. LEXIS 158, at *9; *Paice*, 2006 U.S. Dist. LEXIS 61600, at *16-*17; *z4 Techs., Inc. v. Microsoft Corp*., 434 F. Supp. 2d 437, 442-43 (E.D. Tex. 2006).

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– especially when combined with the adverse affect on the public health (*see supra* Part IV.B), the "close call" regarding claim construction (*see supra* Part IV.A.5.a), reexamination by the PTO[23] (*see supra* Part IV.A.5.b.), and the other factors identified above (*see supra* Part IV.A.1-4) – weighs heavily against an injunction. *See Cordis*, 2003 U.S. Dist. LEXIS 21338, at *6 (denying a preliminary injunction even though the patent holder was likely to succeed on the merits, in part, because "an injunction would likely cut [the infringer's] workforce [and] threaten its most important business"); *Tensar Corp. v. Tenax Corp.*, 24 USPQ.2d 1605, 1614 (D. Md. 1992) (finding that the balance of the hardships tipped in favor of the defendant because the defendant would have to lay off personnel if it was ordered to cease selling the accused products, whereas, if the patent holder lost business to the accused products, these losses would be fully compensable by an award of damages); *Am. Cyanamid Co.*, 833 F. Supp. at 125 (denying a preliminary injunction, in part, because the potential for job losses at the infringer if its product was enjoined was greater than the potential for job losses at the patent holder if the injunction was not granted).

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[23] On remand, the trial court in *eBay* recognized the "substantial risk of harm" to the defendant, where the patent-in-suit twice had been rejected by the PTO and was currently the subject of reexamination hearings, if the court enjoined the patented technology and the defendant lost customers only to later have the patent invalidated by the PTO. *MercExchange*, 500 F. Supp. 2d at 585.

D. ACS's Unclean Hands Preclude It From Obtaining Equitable Relief Against Medtronic

Alternatively, the Court should exercise its equitable discretion to deny the Injunction Motion because there is substantial evidence of ACS's unclean hands in this case. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) (noting that "'he who comes into equity must come with clean hands.'") (citation omitted).

The pertinent facts, to which a more lenient standard applies (the equitable doctrine of unclean hands, rather than the patent doctrine of inequitable conduct) are straightforward:

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ACS used this information to prepare its own Lau stent patent applications and intentionally concealed this fact not only from Boneau but also from the PTO.

These facts were addressed at length in the inequitable conduct trial and in Medtronic's post-trial brief. (*See* D.I. 683 at 7-14, 17-20, 33-40; D.I. 687 at 2-7.) The Court did not reach the question of whether ACS intended to deceive the PTO by its concealment of the Boneau patent application, however, given the Court's finding that it was ultimately cumulative to U.S. Patent No. 5,102,417 (Palmaz). The Court's ruling, therefore, did not address whether ACS acted deliberately to suppress what it viewed *at the time* to be relevant prior art – *i.e.*, whether ACS acted with unclean hands. Indeed, this Court has ruled, and the PTO has now specifically determined in preliminarily rejecting certain asserted claims, that the disclosures in the Boneau patent application *were* material prior art. (*See* D.I. 713 at 15-17; Louden Decl. Ex. K at 6, 37, 51, 54.)

Significantly, the doctrine of "unclean hands" for purposes of this Injunction Motion is broader than the concept of inequitable conduct before the PTO for purposes of the now-concluded trial in this case. Inequitable conduct requires proof by clear and convincing evidence of materiality and of a failure to disclose material information to the PTO with an intent to deceive. *See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988). By contrast, the requirements for finding unclean hands are not nearly so restrictive. As the Supreme Court has explained: "This maxim [unclean hands] necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant. It is 'not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.'" *Precision Instrument*, 324 U.S. at 814 (citations omitted). Accordingly, a court may deny a patent holder equitable relief based on unclean hands, even where the patent holder's actions did not constitute "inequitable conduct" to render the patent unenforceable. *See Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1378 (Fed. Cir. 2001).

The doctrine of unclean hands also extends to the patentee's conduct beyond the PTO, including in the litigation context. In *Aptix*, for example, the Federal Circuit held that the patentee's litigation misconduct – falsifying notebook pages – warranted dismissal of the case, even though it did not constitute "inequitable conduct before the PTO" rendering the patent itself unenforceable. *Aptix*, 269 F.3d at 1377.

In this case, ACS committed litigation misconduct by improperly beginning its cross-examination of Mr. Boneau at trial with allegations of "false testimony" – in direct violation of the Court's order on a prior motion *in limine*. (D.I. 636 at 1221:9-1234:6 (attached as Louden Decl. Ex. U).) The Court determined that ACS's actions were so "untenable" that it ordered the cross-examination "stricken" and excused Mr. Boneau from any further examination. (*Id.* at

1229:10-12, 1233:22-1234:4.) Further, as noted above, ACS appears to have timed its Injunction Motion and leaked it to Morgan Stanley on the eve of Medtronic's announcement of the successful results of its late-stage clinical trial for its Endeavor drug-eluting stent. *Cf. Century Time, Ltd.*, 729 F. Supp. at 368 ("We simply cannot tolerate tactical maneuvering, in injunction matters, whereby parties sit back and wait for what they believe to be timing most injurious to the procedural fairness for their adversaries.").

ACS's unclean hands therefore constitute an independent basis to deny an injunction here.

V. CONCLUSION

For the reasons set forth above, Medtronic Vascular, Inc. and Medtronic USA, Inc. respectfully request that the Court deny ACS's Motion for a Permanent Injunction.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden
Karen Jacobs Louden (#2881)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Defendants Medtronic Vascular, Inc and Medtronic USA, Inc.

OF COUNSEL:

Kevin S. Rosen
Matthew A. Hoffman
Anthony S. Newman
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071-3197
(213) 229-7000

H. Mark Lyon
Frederick S. Chung
GIBSON, DUNN & CRUTCHER LLP
1881 Page Mill Road
Palo Alto, CA 94304-1211
(650) 849-5300

November 1, 2007

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 8, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to Frederick L. Cottrell, III.

I further certify that on November 8, 2007 I served copies of the foregoing to the following counsel in the manner indicated:

BY HAND & EMAIL

Frederick L. Cottrell, III
Anne Shea Gaza
Richards Layton & Finger
One Rodney Square
P.O. Box 551
Wilmington, DE 19899

BY EMAIL

J. Michael Jakes
Michael A. Morin
Finnegan Henderson Farabow Garrett & Dunner LLP
901 New York Avenue, NW
Washington, DC 20001-4413

/s/ Karen Jacobs Louden

klouden@mnat.com